13th Annual NIH SBIR/STTR Conference
Translating Medical Discoveries into Health Products

DAY 1, SUBMISSION, POLICIES, PROCEDURES

WEDNESDAY, JUNE 22, 2011 Plenary Sessions in Main Auditorium Concurrent Sessions in Rooms as Noted	
7:30 am	**REGISTRATION OPENS**
7:30 - 8:00 am	**CONTINENTAL BREAKFAST** Enjoy a light breakfast as you look over the Program materials.
8:00 - 8:15 am	***Welcome*** *Dr. Matthew Portnoy* *NIH SBIR/STTR Program Manager*
8:15 – 9:00 am	***Keynote*** *TBD*
9:00 – 9:45 am	***Overview and Update of the NIH SBIR/STTR Program*** *Dr. Matthew Portnoy* *NIH SBIR/STTR Program Manager* The NIH SBIR and STTR programs offer many opportunities for small companies to do innovative research in the life and health sciences. In this session, Dr. Matthew Portnoy, NIH SBIR/STTR Program Manager, will provide a general overview of the programs touching on topics such as eligibility requirements, the NIH SBIR/STTR budget, submission, review, when and how to communicate with the NIH staff, Phase III assistance programs, etc. Flexibility is key to the success of NIH's programs and along with that comes many nuances (both programmatically and procedurally) for which applicants must be aware. The times are ever changing and NIH is no exception as it implements new policies and procedures, so don't miss out on the latest updates.
9:45 -10:00 am	**BREAK**
10:00 - 10:45am	***NIH SBIR/STTR Receipt and Referral Processes*** *Dr. Laura Roman, Associate Director,* *Receipt & Referral Office, Center for Scientific Review* Are you asking yourself questions like: What are critical policies and requirements for submission? How, when, and by whom will my application be reviewed? What Institutes/Centers will consider it for funding? Who may I contact for assistance during the review period? Dr. Laura Roman, Associate Director of the Division of Receipt and Referral of the Center for Scientific Review (CSR) will answer these questions as she methodically guides you through the receipt and referral processes.
10:45 -11:30 am	***NIH SBIR/STTR Review Process*** *Dr. Larry Boerboom, Scientific Review Officer* *Center for Scientific Review* Over the past several years, NIH embarked upon a trans-NIH Enhancing Peering Review Initiative resulting in the successful implementation of many internal and external stakeholders' recommendations to enhance the NIH peer review system. These resulted in such things as deploying a new scoring system, using new templates for reviewer critiques, shortening the length of applications, and restructuring the research strategy section to align with the five NIH-wide review criteria. This session will begin with a video of a mock review session that shows first-hand how the scientific and technical merit of an application is determined and provides insight about what reviewers expect to see for each of the review criteria. Grantsmanship tips from the reviewer's perspective will also be provided. Plenty of

	time is allotted for an engaging discussion based on audience questions & answers (Q&As).	
11:30am-12:30pm	**LUNCH**	
12:30 – 2:00 pm	**CONCURRENT SESSIONS**	
	Main Auditorium *(Session runs from 12:30 – 1:15 pm)*	***Preparing A Successful Application in a Competitive Environment—Tales from the Trenches*** *Facilitator: Dr. Jerry Wujek, National Eye Institute* *Panelists: TBD* Although this panel includes small companies who have received NIH SBIR and/or STTR awards, not all of their applications have been successful. Some were funded based on their initial submission, others after revising and resubmitting and others just didn't make it at all. As changes take place in the economy and in the peer review process, competition for grants has become tougher. Take advantage of the tips shared by these panelists about their up-and-down experiences and learn how best to approach the writing of SBIR and STTR grants for NIH evaluation.
	Main Auditorium *(Session runs from 1:15 – 2:00)*	**Post Award Compliance for SBIR/STTR Grantees** *John Burke, Lisa Scott-Morring, Division of Grants Compliance and Oversight, OPERA, OER* NIH and its grant recipients share responsibility for compliance and oversight to ensure proper stewardship of Federal funds. To fulfill this administrative partnership, the NIH provides "compliance assistance" that consists of clear and easy-to-access information on federal grants financial and management requirements for contractors, grantees, and the public. Compliance assistance is crucial to the successful administration and fiscal management of grant awards and it safeguards the Federal investment in America's R&D efforts. This session will address the administrative requirements, cost principles, and audit requirements applicable to SBIR/STTR grants.
	Balcony A *(Session runs from 12:30 – 2:00 pm)*	***NIH Resources for Small Business Success*** *CTSA's: Dr. Jody Sachs, National Center for Research Resources* *Molecular Libraries: Dr. Carson Loomis, National Human Genome Research Institute* *TRND/RAID: TBD* *HTOR: Dr. John Lonsdale, National Disease Research Interchange* While the NIH is the major agency providing funding for biomedical research, did you know that it also provides resources to the biomedical community that can help accelerate research? Come to this session to learn about some of the resources available including the *Molecular Libraries and Imaging* program (ML), the *Therapeutics for Rare and Neglected Diseases(TRND)* and the *Rapid Access to Interventional Development(RAID)* program, the *Clinical and Translational Science Awards (CTSA)*, and the *Human Tissues and Organs Resource for Research (HTOR).* Hear how small businesses have used these opportunities to help leverage their research and development programs. **Note**: these examples are illustrative of opportunities available at NIH. In addition, individual institutes may have other resources available. For information on these institute-specific resource opportunities for small businesses, visit the one-on-one sessions.
	Balconies B&C *(Session runs*	**Successfully Submitting Your Grant Application Electronically** *Sam Smith, eRA Help Desk, Documentation, Training and Testing*

	from 12:30 – 2:00 pm)	*Support* Did you know that nearly 1/3 of all small business applicants submit applications with errors that require correction by the deadline? In this session, we'll explore the process applicants must follow to prepare, submit, track and verify their electronic submission. Along the way, we'll provide valuable tips and resources to help small businesses achieve error-free applications and a successful submission!
	Rooms C, E, F, G *(Session runs from 12:30 – 2:00 pm)*	**One-on-Ones with NIH/CDC/FDA Staff** Meet with staff from the NIH, CDC, and FDA and get answers to your specific questions.
2:00 – 2:45 pm	**CONCURRENT SESSIONS**	
	Main Auditorium	**Identifying NIH SBIR/STTR Funding Opportunities** *Dr. Matthew Portnoy* *NIH SBIR/STTR Program Manager* NIH is a large, complex, yet flexible organization which offers many opportunities for research funding, but how can you identify those of interest to you? Since NIH offers both SBIR and STTR grant and contract opportunities, this session will address both and teach you the differences between grants and contracts, how to find these opportunities, how to determine which are best for you, and how to stay informed of all research funding opportunities available to small companies.
	Balcony A	**Facilitating Translation Through Industry-University Collaborations** *Michael Amey, Associate Dean, Research Administration, Johns Hopkins University, School of Medicine* *Additional Speaker: TBD* Universities represent an excellent source of knowledge creation and invention, and many small businesses seek to enhance their research and technical expertise by partnering with academia. In order to gain formal access to university resources, a small business must work with the appropriate university officials. During this session, the presenters will discuss the process of establishing industry-university collaborations, toward the goal of maximizing the small business's own technology and innovation pipeline.
	Balconies B&C	**A Look Into the NIH, CDC, FDA Institutes and Centers** Scientific priority areas of the individual institutes and centers that may be of interest to small business research applicants will be highlighted during these sessions. The institute and center representatives will also discuss research funding opportunities and technical resources that are available to small businesses beyond the SBIR/STTR program. Topics of discussion will include programs that encourage collaborating with SBIR/STTR communities, non-SBIR/STTR funding opportunities/mechanisms, resources available to the extramural research community, and NIH collaboration mechanisms.
	Rooms C, E, F, G	**One-on-Ones with NIH/CDC/FDA Staff** Meet with staff from the NIH, CDC, and FDA and get answers to your specific questions.

2:45 - 3:45 pm	**NETWORKING/POSTER SESSION**	
3:45 – 5:15 pm	**CONCURRENT SESSIONS**	
	Main Auditorium *(Session runs from 3:45 – 5:15 pm)*	**Indirect Cost Rates and Accounting Systems** *Lorraine Trexler & Ray Woodward, Division of Financial Advisory Services* Don't leave money on the table! This is a workshop designed to teach participants how to develop basic indirect cost rates. It will address such topics as why indirect cost rates are vital to a company's fiscal success and explore fundamental accounting system issues that you need to be aware of prior to award.
	Balcony A *(Session runs from 3:45 – 4:30 pm)*	**Research Involving Human Subjects** *Maria Stagnitto, Human Research Protection Officer, Office of Extramural Programs* Need some insights on how to address research involving Human Subjects in your grant application? This session provides valuable information on this and other topics, including an overview of HHS regulations, NIH policies and guidance for research involving human subjects.
	Balcony A *(Session runs from 4:30 – 5:15 pm)*	**Research Involving Animals: OLAW – Office of Laboratory Animal Welfare** *Patricia Brown, VMD, Office of Laboratory Animal Welfare* Are you considering using live vertebrate animals in your research? Are you aware that the policies and regulations regarding research animals are different than those involving human subjects? This session provides information on 1) the requirements for using animals, 2) appropriate completion of the Vertebrate Animal Section of the grant application and peer review considerations, 3) the functions of an Institutional Animal Care and Use Committee, 4) details on the various Assurance documents including which type is required if your institution does not have its own animal facility, and 5) the consequences of what happens when animal activities become noncompliant.
	Balconies B&C *(Session runs from 3:45 – 4:30 pm)*	**Products, Partners & Public Health - - Commercializing New Technologies *from* NIH** *Steve Ferguson, Office of Technology Transfer* The focal point for U.S. government investment in innovative healthcare research and development has been the National Institutes of Health (NIH). The intramural research program itself at the NIH has led to a huge variety of novel basic and clinical research discoveries – all of which require commercial partners in order to develop them into products for hospital, physician or patient use. With over half of new NIH license agreements granted to small firms and over 600 products (including 24 FDA-approved drugs and vaccines) launched by NIH licensees, working with technologies from the intramural NIH & FDA research programs cannot be overlooked as part of any long-term growth strategy for biomedical firms. This session will discuss ways in which SBIR firms can partner with NIH, including the new pilot NCI SBIR – Tech Transfer Program which combines an SBIR award with a license to an underlying intramural technology to accelerate product development.

	Balconies B&C *(Session runs from 4:30 – 5:15)*	**A Look Into the NIH, CDC, FDA Institutes and Centers** Scientific priority areas of the individual institutes and centers that may be of interest to small business research applicants will be highlighted during these sessions. The institute and center representatives will also discuss research funding opportunities and technical resources that are available to small businesses beyond the SBIR/STTR program. Topics of discussion will include programs that encourage collaborating with SBIR/STTR communities, non-SBIR/STTR funding opportunities/mechanisms, resources available to the extramural research community, and NIH collaboration mechanisms.
	Rooms C, E, F, G *(Session runs from 3:45 – 5:15 pm)*	**One-on-Ones with NIH/CDC/FDA Staff** Meet with staff from the NIH, CDC, and FDA and get answers to your specific questions.
5:15 - 5:30 pm	**Wrap-Up: Day One** *Dr. Matthew Portnoy* *NIH SBIR/STTR Program Manager*	

THURSDAY – JUNE 23, 2011		
7:30 - 8:00 am	**CONTINENTAL BREAKFAST** Enjoy a light breakfast as you prepare for your second day.	
8:00 – 9:30 am	**CONCURRENT SESSIONS**	
	Main Auditorium	**Strategies for Commercialization: Building a Business Roadmap to Success** *Speaker, TBD* Are you a researcher who is having difficulty with entrepreneurial thinking? Are you struggling with how to start, finance, and build your business? Should you be investing more "sweat equity" into your company or should you perhaps consider obtaining venture capital, angel, or corporate investors? Is licensing a viable option? Understanding the current commercialization environment of your specific industry sector and your personal vision for the technology and your company's growth affects the decisions you'll make with bringing your SBIR/STTR-developed innovation to the marketplace. Attend this session to begin to design your "business roadmap to success."
	Balcony A	**Indirect Cost Rates and Accounting Systems (repeat of previous day)** **Indirect Cost Rates and Accounting Systems** *Lorraine Trexler & Ray Woodward, Division of Financial Advisory Services* Don't leave money on the table! This is a workshop designed to teach participants how to develop basic indirect cost rates. It will address such topics as why indirect cost rates are vital to a company's fiscal success and explore fundamental accounting system issues that you need to be aware of prior to award.
	Balconies B&C	**Successfully Submitting Your Grant Application (repeat of previous day)** *Sam Smith, eRA Help Desk, Documentation, Training and Testing Support* Did you know that nearly 1/3 of all small business applicants submit applications with errors that require correction by the deadline? In this session, we'll explore the process applicants must follow to prepare,

		submit, track and verify their electronic submission. Along the way, we'll provide valuable tips and resources to help small businesses achieve error-free applications and a successful submission!
	Rooms C, E, F, G	**One-on-Ones with NIH/CDC/FDA Staff** Meet with staff from the NIH, CDC, and FDA and get answers to your specific questions.
9:30 – 10:15 am	**CONCURRENT SESSIONS**	
	Main Auditorium	**Raising Follow-on Capital: Beyond SBIR** *Facilitator: Dr. Gregory Milman, National Institute of Allergy and Infectious Diseases* *Panelists: TBD* In today's life sciences environment, as small businesses look for much-needed capital financing for their sometimes risky ventures, venture capital presents an opportunity to access early and late stage investment from venture funds that focus on life science and biomedical innovations. Panelists will discuss venture capital and angel investor criteria and hurdles required for investment in early stage biotech opportunities. They will also discuss how to prepare for valuation, raising risk capital, differences in stages of investment and the due diligence process.
	Balcony A	**TBD**
	Balconies B&C	**A Look Into the NIH, CDC, FDA Institutes and Centers** Scientific priority areas of the individual institutes and centers that may be of interest to small business research applicants will be highlighted during these sessions. The institute and center representatives will also discuss research funding opportunities and technical resources that are available to small businesses beyond the SBIR/STTR program. Topics of discussion will include programs that encourage collaborating with SBIR/STTR communities, non-SBIR/STTR funding opportunities/mechanisms, resources available to the extramural research community, and NIH collaboration mechanisms.
	Rooms C, E, F, G	**One-on-Ones with NIH/CDC/FDA Staff** Meet with staff from the NIH, CDC, and FDA and get answers to your specific questions.
10:15 – 10:30 am	**BREAK**	
10:30 – 11:15 am	**CONCURRENT SESSIONS**	
	Main Auditorium	**Building Corporate Alliances & Partnerships** *Jason Adair, Director, Business Development, MedImmune LLC* Building alliances to help commercialize biotechnology and health-related products can be more difficult than obtaining the funding to do the research, especially in these economic hard times. It's almost impossible to go it alone. This session will equip small businesses with the knowledge on building their phase III strategies for bringing their technologies to the marketplace through building alliances and partnerships with corporate partners. Topics will include how to start the relationship-building process and when, advantages and challenges of partnerships including issues that need to be considered when transferring technologies through testing, licensing, partnering, consulting, and overall business development strategies for effective partnering.
	Balcony A	**Interactive Multi-media Panel: Commercialization of Behavioral Services, Interventions and Products**

		Facilitator: Connie Dresser, National Cancer Institute *Panelists: TBD* During this panel session, successful SBIR social-behavioral grantees will explain how they 1) found and engaged potential backers BEFORE submitting a Phase II application, 2) collaborated with potential end-users about production and marketing during their research, 3) addressed barriers to marketing and sealed a deal, and 4) tracked the success of their product in the marketplace.
	Balconies B&C	**A Look Into the NIH, CDC, FDA Institutes and Centers** Scientific priority areas of the individual institutes and centers that may be of interest to small business research applicants will be highlighted during these sessions. The institute and center representatives will also discuss research funding opportunities and technical resources that are available to small businesses beyond the SBIR/STTR program. Topics of discussion will include programs that encourage collaborating with SBIR/STTR communities, non-SBIR/STTR funding opportunities/mechanisms, resources available to the extramural research community, and NIH collaboration mechanisms.
	Rooms C, E, F, G	**One-on-Ones with NIH/CDC/FDA Staff** Meet with staff from the NIH, CDC, and FDA and get answers to your specific questions.
11:15 – 12:00 pm	**CONCURRENT SESSIONS**	
	Main Auditorium	**Protecting Your Intellectual Property through iEdison Invention Reporting** *J.P. Kim, JD; OPERA, NIH* Inventions made under a federal research award can be a company's most valuable asset if properly identified and managed. But while many may embark upon the road to commercialization, the successful journey needs a roadmap to avoid any roadblocks and potholes along the way. Effective and timely protection of intellectual property rights is of paramount importance for ensuring marketing and commercialization success. Practical information about protecting and commercializing those rights will be provided.
	Balcony A	**Commercializing Your Healthcare/IT/Media Product** *Shahid Shah, Netspective* Each year thousands of healthcare-related products are created but only some of them become commercial successes; almost all of the ones that make it to the market, get sold, and are ultimately deployed have some common characteristics. Shahid will describe some of those characteristics and help you find ways of getting the attention of your customers, explaining your product to them in a concise and meaningful way, devising pricing and partnering strategies, and finally figuring out how to get paid for what you've created. It's difficult to have your product's messaging make it through the noise in an ordinary market – but, of course we're not living in ordinary times so things are even harder. Shahid will help you devise the right strategies so that you can rise above the herd and get noticed in the marketplace
	Balconies B&C	**A Look Into the NIH, CDC, FDA Institutes and Centers** Scientific priority areas of the individual institutes and centers that may be of interest to small business research applicants will be highlighted

		during these sessions. The institute and center representatives will also discuss research funding opportunities and technical resources that are available to small businesses beyond the SBIR/STTR program. Topics of discussion will include programs that encourage collaborating with SBIR/STTR communities, non-SBIR/STTR funding opportunities/mechanisms, resources available to the extramural research community, and NIH collaboration mechanisms.
	Rooms C, E, F, G	**One-on-Ones with NIH/CDC/FDA Staff** Meet with staff from the NIH, CDC, and FDA and get answers to your specific questions.
12:00p.m. – 1:30p.m.	**LUNCH**	
1:30 – 2:15 pm	**CONCURRENT SESSIONS**	
	Main Auditorium	**Overview of Regulatory Requirements: Medical Devices** *Carole Carey, Center for Devices and Radiological Health, FDA* FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States. In addition, CDRH regulates radiation-emitting electronic products (medical and non-medical) such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions. This presentation will primarily address FDA's medical device rules and regulations. Basic regulatory requirements that manufacturers of medical devices must comply with in order to legally market a medical device in the United States will be presented. This includes a discussion on the definition of a medical device; medical device classification, establishment registration and listing; premarket applications [510(k) and PMA]; as well as postmarketing activities. Valuable resources that will assist small manufacturers on how to comply with FDA's medical device regulations will also be provided.
	Balcony A	**Leveraging State Resources** *Robert Brown, Virginia's Center for Innovative Technologies* *Robbie Melton, Maryland Technology Development Corporation* Unbeknownst to many, a wealth of SBIR/STTR information and support is often available right in your own backyard. Many state organizations are available and interested in assisting you with applying for an SBIR or STTR grants/contract, and some actually have funding available to help defer the costs of preparing an application. Join this group to learn specifically about the various resources available in Maryland and Virginia and also learn where and how to look for opportunities in your state.
	Balconies B&C	**Overview of Regulatory Requirements: Pharmaceuticals** *Dr. Mary Kremzner, Center for Drug Evaluation and Research, FDA* The Center for Drug Evaluation and Research (CDER) performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This work covers more than just medicines. For example, fluoride toothpaste, antiperspirants, dandruff shampoos and sunscreens are all considered "drugs." The presentation by the Division of Drug Information, CDER, will address the regulatory requirements for the approval of new drugs; generic drug approval process; overview of over-the-the counter drugs; listing and registration of product and

		companies with the agency; and small business assistance programs and resources for information.
	Rooms C, E, F, G	**One-on-Ones with NIH/CDC/FDA Staff** Meet with staff from the NIH, CDC, and FDA and get answers to your specific questions.
2:15 – 3:00 pm	**CONCURRENT SESSIONS**	
	Main Auditorium	**NIH Technical Assistance Programs** *Dr. Lenka Fedorkova, NIH SBIR/STTR Program* You thought being selected for an award was difficult, but getting to the marketplace can be even more challenging. Biomedical research can take millions of dollars and 10+ years before a product reaches consumer hands. So how are you planning to get over this huge hurdle? NIH offers several assistance programs to help SBIR awardees strategize how to commercialize their SBIR-developed products. Join this session to find out what programs might be available for you and how to become involved.
	Balcony A	**Moving from R&D to Manufacturing: Resources Available from NIST Manufacturing Extension Partnership Program** *Clara Asmail, Manufacturing Extension Partnership, NIST* Manufacturing is a later stage of commercialization, however, it is something that companies should begin to think about during Phase 1. Especially as they formulate the commercialization plan for the Phase 2 proposal and during the R&D stages, SBIR/STTR need to plan their strategy for producing the products they develop. Choice of a manufacturing strategy can have a long-term impact on finances, corporate strategy and the lifestyle of the corporate leaders. This session will discuss the core scale-up and production strategies life science companies employ that can reduce costs and time to market while meeting quality and regulatory requirements as well as a corporate strategy. Examples will be drawn from NIH SBIR awardees.
	Balconies B&C	**A Look Into the NIH, CDC, FDA Institutes and Centers** Scientific priority areas of the individual institutes and centers that may be of interest to small business research applicants will be highlighted during these sessions. The institute and center representatives will also discuss research funding opportunities and technical resources that are available to small businesses beyond the SBIR/STTR program. Topics of discussion will include programs that encourage collaborating with SBIR/STTR communities, non-SBIR/STTR funding opportunities/mechanisms, resources available to the extramural research community, and NIH collaboration mechanisms.
	Rooms C, E, F, G	**One-on-Ones with NIH/CDC/FDA Staff** Meet with staff from the NIH, CDC, and FDA and get answers to your specific questions.
3:00 – 3:30 pm	**Wrap-Up & Adjourn** *Dr. Matthew Portnoy* *NIH SBIR/STTR Program Manager*	